

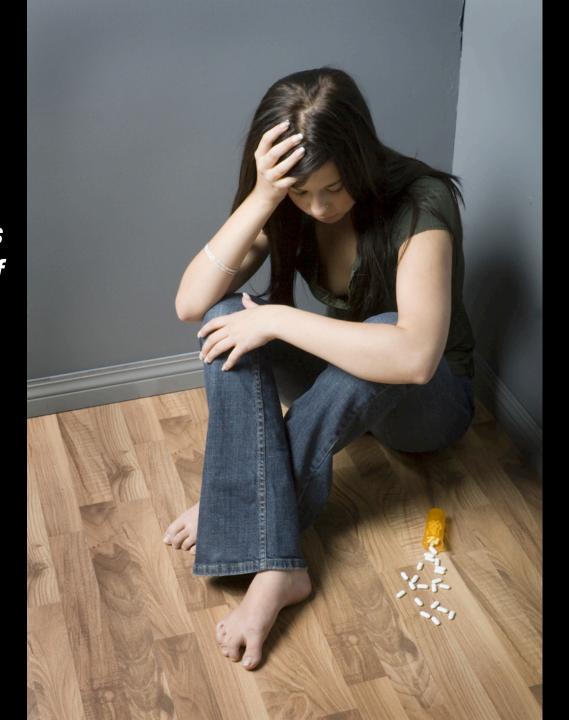
A Hidden Epidemic: Neonatal Abstinence Syndrome

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Advance Practice Coordinator
Pediatrix Medical Group
East TN Children's Hospital
October 30th, 2013

Dr. Thomas Freiden Director of the Centers for Disease Control

"When I was in medical school.... I was told...if you give opiates to a patient who's in pain, they will not get addicted. Completely wrong... A generation of us grew up being trained that these drugs aren't risky. In fact, they are risky"

Addiction is a disease of the brain, NOT A moral failure





Tolerance – Dependence – Addiction

Tolerance

 Our body develops tolerance to a drug's effect so that an increased amount of drug is required to produce effect.

Dependence

 If the supply of the drug is removed then the person will exhibit "withdrawal symptoms".

Addiction

 The continuing, compulsive nature of the drug use despite physical and/or psychological harm to the user and society

BEHAVIORAL

DOPAMINE

- Catecholamine
- Chemical neurotransmitter
- Sends signals to nerve cells
- Produced in several areas of the brain
- Responsible for reward-driven learning
 - Allows body to sense pleasure

The Dopamine Pathway

- The brain contains a natural reward system (limbic system)
- · This increases temporary levels of dopamine
 - Natural triggers
 - Food
 - Exercise
 - Sex
 - Nurturing children

Why is this important?

Drugs activate the same system activated by natural rewards

BUT...drugs activate the system stronger and longer

Drugs "hijack" the brains dopamine system and the brain becomes dependent on the drug

Natural rewards no longer produce the desired dopamine levels which result in a feeling of pleasure

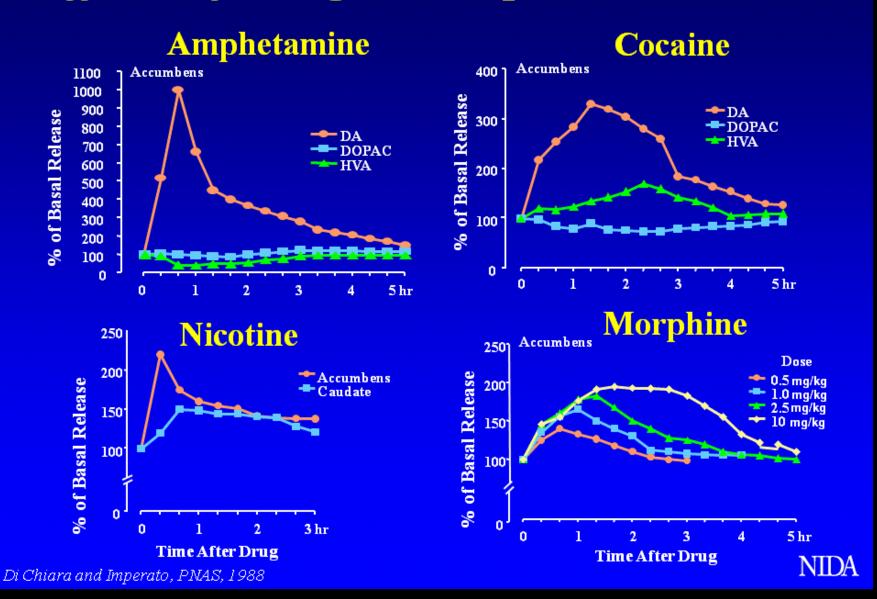
EVOLUTION OF ADDICTION

After a while, use of a drug leads to an adaptation in the brain

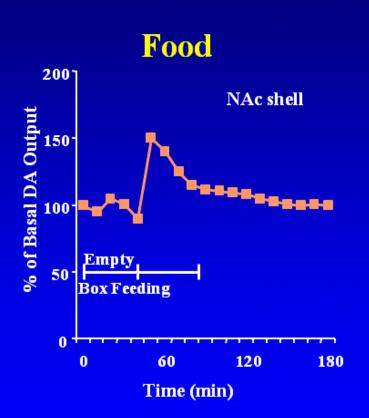
Brain expects higher levels of dopamine

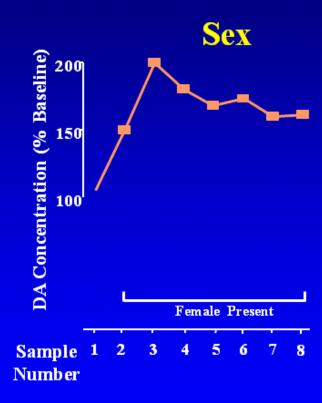
The deficit in dopamine causes an inability to feel pleasure, except through drug use

Effects of Drugs on Dopamine Release



Natural Rewards Elevate Dopamine Levels





Epidemiology

- NIDA estimates \$600 billion is spent annually on costs associated with substance abuse in U.S.
 - American Diabetes Association estimates annual costs associated with diabetes is \$174 billion in 2007.
 - National Cancer Institute estimates \$125 billion in annual costs for cancer care in 2010.
 - Projected 220 billion gym
- 2009 National Survey on Drug Use and Health:
 - 4.5 percent of pregnant women aged 15 to 44 have used illicit drugs in the past month.
 - In 2008 there were 9430 babies born in Knox County according to Knox County hospitals birth records: Estimated 424 babies born annually in Knox County whose mother used illicit drugs in the past month.
- 2009 Key Birth Stats from CDC report 4,131,019 births in U.S.
 - Approximately 186,000 babies born to mothers who used illicit drugs in past month
- NIDA InfoFacts: Understanding Drug Abuse and Addiction. National Institute on Drug Abuse. http://www.drugabuse.gov/infofacts/understand.html. Accessed May 28, 2011
- Diabetes Cost Calculator. American Diabetes Association. http://www.diabetesarchive.net/advocacy-and-legalresources/cost-of-diabetes.jsp. Accessed May 28, 2011.
- The Cost of Cancer. National Cancer Institute. http://www.cancer.gov/aboutnci/servingpeople/cancer-statistics/costofcancer. Accessed May 28, 2011.
- 4. Substance Abuse and Mental Health Services Administration. (2010). Results from the 2009 National Survey on Drug Use and Health: Volume I. Summary of National Findings (Office of Applied Studies, NSDUH Series H-38A, HHS Publication No. SMA 10-4856Findings). Rockville, MD.
- Number of Babies Born. Kids Count Data Center. http://datacenter.kidscount.org/data/bystate/Rankings.aspx?state=TN&ind=2996. Accessed May 27, 2011.

Drug-induced deaths exceed MVA deaths

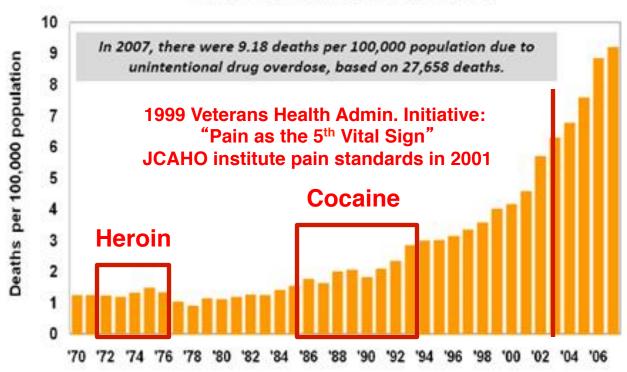
25 Deaths per 100,000 population Motor vehicle traffic Poisoning Drug poisoning 1980 1984 1988 1992 1996 2000 2004 2008 Year

Figure 1. Motor vehicle traffic, poisoning, and drug poisoning death rates: United States, 1980–2008

NOTE: In 1999, the International Classification of Diseases, Tenth Revision (ICD-10) replaced the previous revision of the ICD (ICD-9). This resulted in approximately 5% fewer deaths being classified as motor-vehicle traffic-related deaths and 2% more deaths being classified as poisoning-related deaths. Therefore, death rates for 1998 and earlier are not directly comparable with those computed after 1998. Access data table for Figure 1 at http://www.cdc.gov/nchs/data/databriefs/db81 tables.pdf#1. SOURCE: CDC/NCHS, National Vital Statistics System.

Warner M, Chen LH, Makuc DM, Anderson RN, Miniño AM. Drug poisoning deaths in the United States, 1980–2008. NCHS data brief, no 81. Hyattsville, MD: National Center for Health Statistics. 2011.

Unintentional Drug Overdose Deaths United States, 1970-2007



Source: Centers for Disease Control and Prevention. Unintentional Drug Poisoning in the United States (July 2010).

Pain the 5th Vital Sign

1980s: Dr. Russell Portenoy lead drive to expand use of opiods

Risk of addiction felt to be less than 1%

1886 paper 38cases supported safety of opiods outside end of life care

American Pain Society campaign "Pain as the 5th Vital Sign"

1998 Federation of State Medical Boards removes regulations on amount of narcotics physicians can prescribe

2004 Federation makes under treatment of pain "punishable"

Joint commission: is no evidence that addiction is a significant issue when persons are given opioids for pain control

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building consensus now is that there is little if any evidence that opioids provide safe and effective treatment for chronic noncancer pain, and that paradoxical, underappreciated conditions such as opioid-induced hyperalgesia and narcotic bowel syndrome can complicate long-term treatment. -

See more at: http://www.thepoisonreview.com/2012/12/16/the-money-and-influence-behind-pain-as-a-fifth-vital-sign/#sthash.qtbKs3s7.dpuf



Reform Drug Policy

- PREVENT drug use before it ever begins through education
- 2) EXPAND access to treatment for Americans struggling with addiction
- 3) REFORM our criminal justice system to break the cycle of drug use, crime, and incarceration while protecting public safety
- SUPPORT Americans in recovery by lifting the stigma associated with those suffering or in recovery from substance use disorders

Drug policy is a public health issue, not just a criminal justice issue.

SPREAD THE WORD

NATIONAL DRUG CONTROL STRATEGY

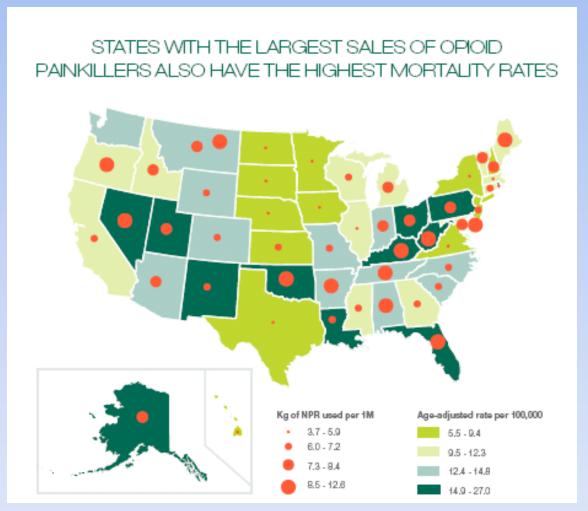
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www.wh.gov/DrugPolicyReform

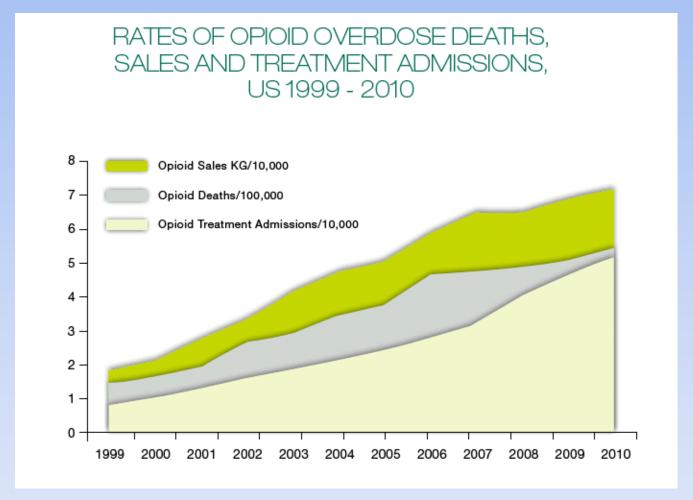
#DrugPolicyReform

Prescription Nation: Addressing America's Prescription Drug Epidemic Report from the National Safety Council, October 14, 2013



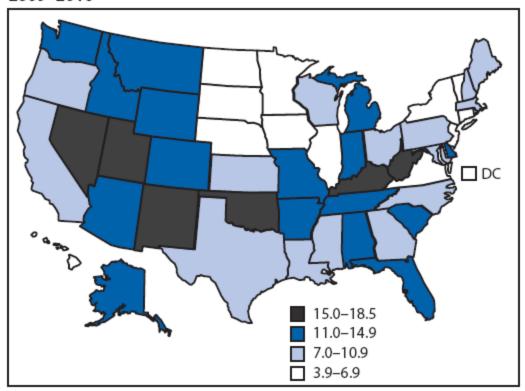
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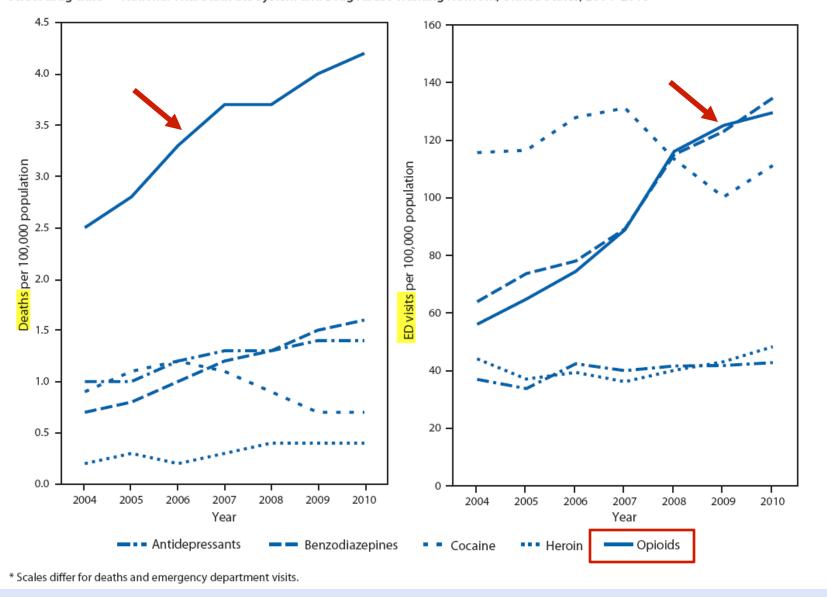
FIGURE 1. Age-adjusted death rates* for drug overdose deaths among women — National Vital Statistics System, United States, 2009–2010



^{*} Deaths per 100,000 population; age-adjusted to the 2000 U.S. standard population using the bridge-race estimates.

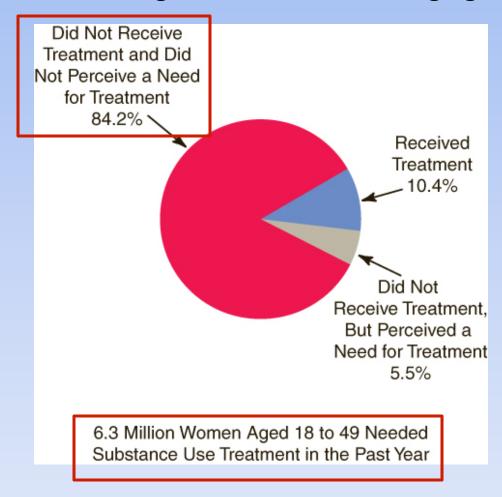
Centers for Disease Control and Prevention. Vital Signs: Overdoses of Prescription Opioid Pain Relievers and Other Drugs Among Women—United States, 1999-2010. MMWR. July 2, 2013;62:1-6.

FIGURE 2. Crude rates* for drug overdose deaths and drug misuse- or abuse-related emergency department (ED) visits among women, by select drug class — National Vital Statistics System and Drug Abuse Warning Network, United States, 2004–2010



Centers for Disease Control and Prevention. Vital Signs: Overdoses of Prescription Opioid Pain Relievers and Other Drugs Among Women—United States, 1999-2010. MMWR. July 2, 2013;62:1-6.

Substance Use Treatment among Women of Childbearing Age



Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (October 4, 2007). *The NSDUH Report: Substance Use Treatment among Women of Childrearing Age*. Rockville, MD.

Narcotics and Contraceptive Use: TennCare Women, CY2011

Demographics	TennCare Women	Women Prescribed Narcotics (>30 days supplied)	Narcotic Users Rate per 1,000	Women Prescribed Contraceptives and Narcotics	% of Women on Narcotics and Contraceptives	Women Prescribed Narcotics without Contraceptives	% of Women on Narcotics Not on Contraceptives
All Women	299,989	45,774	152.6	8,400	18%	37,374	82%
15 - 20	88,668	3,450	38.9	1,663	48%	1,787	52%
21 - 24	44,877	5,244	116.9	1,758	34%	3,486	66%
25 - 29	53,583	9,883	184.4	2,368	24%	7,515	76%
30 - 34	48,173	10,504	218.0	1,501	14%	9,003	86%
35 - 39	37,194	9,398	252.7	746	8%	8,652	92%
40 - 44	27,494	7,295	265.3	364	5%	6,931	95%



Unintended Pregnancy Among All Women & Opioid Abusers



0.0% 10.0% 20.0% 30.0% 40.0% 50.0% 60.0% 70.0% 80.0% 90.0%100.0%

Data source: For general population: Tennessee Department of Health. Pregnancy Risk Assessment Monitoring System, 2009 Summary Report. Available at: http://hit.state.tn.us/Reports/HealthResearch/PregnancyRisk2009.pdf. For opioid-abusing women: Heil SH et al. Unintended pregnancy in opioid-abusing women. Journal of Substance Abuse Treatment. 2011. March; 40(2): 199-202.

Unintended Pregnancy Among All Women & Opioid Abusers

In TN, women with unintended pregnancy:

- •More likely to have **no preconception counseling** (77.7% vs. 55.4%)
- •More likely to have **short interpregnancy interval** (45.0% vs. 15.6%)
- •More likely to have late or no prenatal care (28.1% vs. 10.9%)
- •More likely to **not take folic acid daily** (82.6% vs. 64.7%)

National sample of opioid-abusing women

•Women with unintended pregnancy 60% more likely to have used cocaine within past 30 days compared to women with intended pregnancy

Prenatal Care is Vital

"Adequate prenatal care often defines the difference between routine and high-risk pregnancy and between good and bad pregnancy outcomes.

Timely initiation of prenatal care remains a problem nationwide, and it is overrepresented among women with substance use disorders. In part, the threat of legal consequences for using during pregnancy and limited substance abuse treatment facilities (only 14 percent) that offer special programs for pregnant women (SAMHSA 2007) are key obstacles to care."

US Dept of Health and Human Services, Substance Abuse and Mental Health Services Administration. Substance Abuse Treatment: Addressing the Specific Needs of Women; TIP 51. DHHS 2009.

Early Intervention

- Window of opportunity
 - "Brief interventions can provide an opening to engage women in a process that may lead toward treatment and wellness."
- Pregnancy creates a sense of urgency to
 - Enter treatment
 - Become abstinent
 - Eliminate high-risk behaviors

Potential Benefit of a Perinatal Substance Abuse Program (Early Start)

- Purpose: cost-benefit analysis of an integrated prenatal intervention program for stopping substance abuse in pregnancy.
- Retrospective study of 49,261 women
- · Kaiser Permanente Northern California
- · Completed questionnaires at OB clinics and had urine screening
- · Costs included: maternal health care (prenatal through 1 year postpartum), neonatal birth hospitalization care, and pediatric health care through 1 year
 - Adjusted to 2009 dollars and mean costs adjusted for age, race, education, income, marital status, and amount of prenatal care.

Goler NC, et al. Early Start: a cost-beneficial perinatal substance abuse program. Obstet Gynecol. 2012 Jan;119(1):102-110.

Early Start

· Mission:

- "to provide women with access to services and support to have an alcohol, tobacco, and drug free pregnancy, allowing the delivery of a healthy baby."
- Goal: Complete abstinence
- Interventions
 - Universal screening of all pregnant women
 - Co-location of a licensed mental health professional in the Department of Obstetrics and Gynecology
 - Linking Early Start appointments with routine prenatal care appointments
 - Educating all women and clinicians

Potential Benefit of a Perinatal Substance Abuse Program (Early Start)

	SAF	SA	S	С
Maternal	\$9,430	\$9,230	\$10,869	\$8,282
Infant	\$11,214	\$11,304	\$16,943	10,416
Total	\$20,644	\$20,534	\$27,812	\$18,698

- Compared SAF and SA to S
- Net cost-benefit averaged \$5,946,741 per year

Goler NC, et al. Early Start: a cost-beneficial perinatal substance abuse program. Obstet Gynecol. 2012 Jan;119(1):102-110.

Is MAT cost-effective?

- For every \$1 spent on addiction treatment programs
 - \$4 to \$7 saved in reduced drug-related crime, criminal justice, and theft
 - Including health-care costs, up to \$12 saved.
 - Other considerations
 - Neonatal abstinence syndrome might be reduced
 - More productive citizens



Reaffirmed 2012

The American College of Obstetricians and Gynecologists

Women's Health Care Physicians

COMMITTEE OPINION

Number 473 • January 2011

Committee on Health Care for Underserved Women

This information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Substance Abuse Reporting and Pregnancy: The Role of the Obstetrician–Gynecologist

Abstract: Drug enforcement policies that deter women from seeking prenatal care are contrary to the welfare of the mother and fetus. Incarceration and the threat of incarceration have proved to be ineffective in reducing the incidence of alcohol or drug abuse. Obstetrician—gynecologists should be aware of the reporting requirements related to alcohol and drug abuse within their states. They are encouraged to work with state legislators to retract legislation that punishes women for substance abuse during pregnancy.

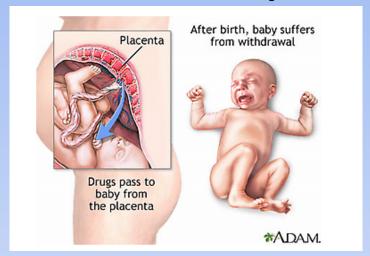


Highlights of HB277 Dunn/SB459 Yager, the Safe Harbor Act:

☐ This bill provides a safe harbor if A woman seeks prenatal care before the 20th week; and If determined to be misusing prescription drugs, initiates appropriate drug treatment expeditiously; Maintains compliance with both prenatal and drug treatment regimens throughout the term of the pregnancy, then DCS would not seek to initiate actions to take the baby solely because of the prescription drug misuse. ☐ Pregnant women would be established as a priority for drug treatment at publicly-funded treatment facilities. ☐ The law specifically permits DCS to take action if other factors exist that could be harmful to the newborn ☐ Provides liability protection for health care providers and facilities who

provide services pursuant to the provisions of the legislation.

Neonatal Abstinence Syndrome (NAS)

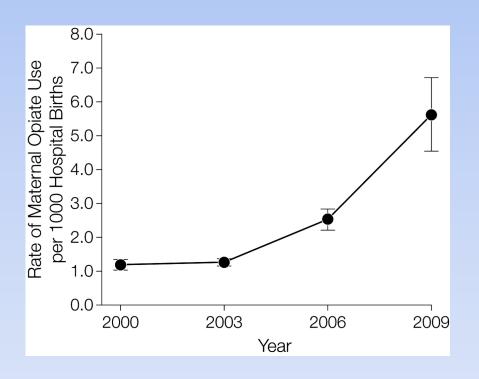


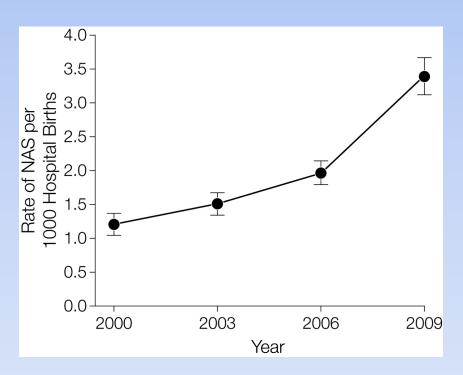
- Constellation of withdrawal symptoms
 - · CNS
 - Inconsolability, high-pitched crying, skin excoriation, hyperactive reflexes, tremors, seizures
 - $\cdot GI$
 - Poor feeding, excessive sucking, feeding intolerance, loose or watery stools
 - Autonomic/metabolic
 - Sweating, nasal stuffiness, sneezing, fever, tachypnea, mottling

Incidence of Maternal Opiate Use and NAS

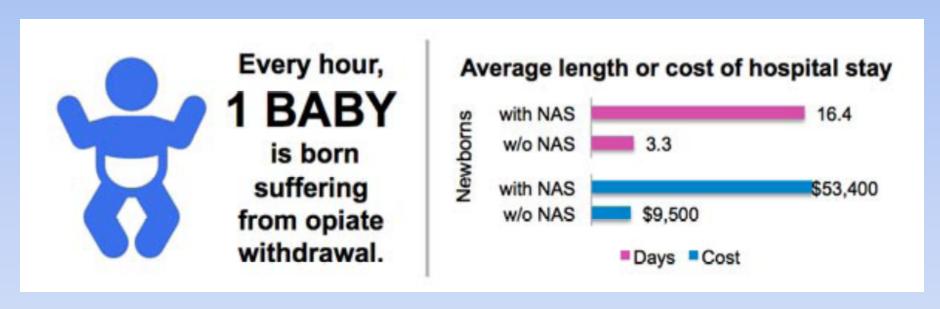
Maternal Opiate Use increased x 5

NAS Incidence tripled



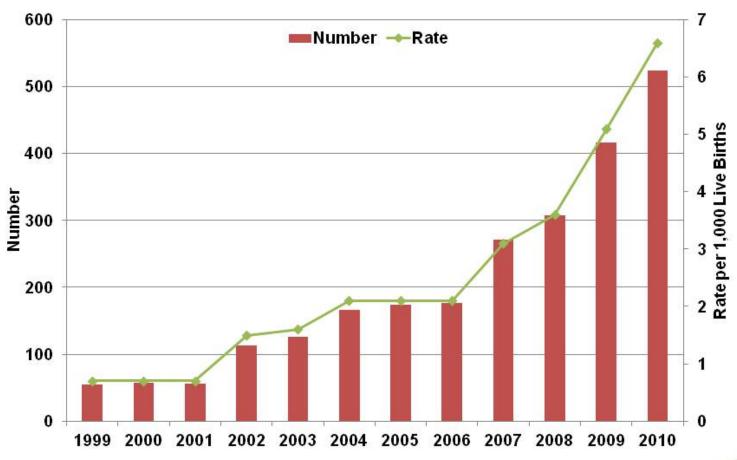


NAS Incidence in the U.S.



Patrick, S. W. et al. JAMA 2012;307:1934-1940

NAS in TN: 1999-2010



Data sources: Tennessee Department of Health; Office of Health Statistics; Hospital Discharge Data System (HDDS) and Birth Statistical System. Analysis includes inpatient hospitalizations with age less than 1 and any diagnosis of drug withdrawal syndrome of newborn (ICD-9-CM 779.5). HDDS records may contain up to 18 diagnoses. Infants were included if any of these diagnosis fields were coded 779.5. Note that these are discharge-level data and not unique patient data.



Current TennCare Costs

Healthy Newborn: \$4,237

NAS Newborn: \$66,973

PREVENTABLE

Tennessee DOH Media Release October 7, 2013

American Academy of Pediatrics (AAP) Guidelines

- * "Reported rates of illicit drug use...underestimate true rates..."
- 55 to 94% of neonates exposed to opioids in utero will develop withdrawal signs.
- Each nursery that cares for infants should develop protocol for screening for maternal substance abuse
- Screening is best accomplished by using multiple methods
 - Maternal history
 - Maternal urine testing
 - Testing of newborn urine/meconium
 - May consider umbilical cord samples

Drug Testing

Types	Results	
In-Office	Immunoassays	Identifies drug class – a few specific drugs
GC/MS	Gas chromatography- mass spectrometry	Identifies specific drugs and metabolites
LC-MS/MS	Liquid chromatography tandem mass spectrometry	Identifies specific drugs and metabolites

- •Meconium
- •Umbilical Cord

AAP Guidelines - Newborn Observation

Risk Factors

- No prenatal care
- ·Limited prenatal care
- ·History of substance use or abuse
- Any positive screen during pregnancy
- Positive UDS on admission

Recommendation

- Observe in the hospital for 4 to 7 days
- Early outpatient followup
 - Reinforce caregiver education about late withdrawal signs

American Academy of Pediatrics (AAP) Guidelines

- Pharmacologic interventions include:
 - oral morphine solution, or methadone as primary therapy
 - Increasing evidence for clonidine as primary or adjunctive therapy
 - Buprenorphine use as primary or adjunctive therapy is also increasing
 - Treatment for polysubstance exposure may include opioid, phenobarbital, and clonidine in combination.

NAS TREATMENT OPTIONS

INPATIENT

No standardized evidence based "Best Practice"

Lengthy

Unique challenges for staff and institution,

Physical and emotional challenges

Multidisciplinary needs

Staff education on Science of Addiction

Interacting with the substance abusing parent

Listen to front line staff

Must be ORGANIZED STANDARDIZED and MULTIDISCIPLINARY

OUTPATIENT

Compliance
Physicians and pharmacies
Custodial changes

Caregiver bias

DIVERSION

Requires: contracts, incentives for compliance, accountability for non-compliance

ETCH Haslam Neonatal Intensive Care Unit

- 152 beds / Level III NICU 60 beds
 - About 30 % of our NICU admissions primarily for NAS treatment
 - 135 admissions for 2011
 - 283 admissions for 2012
 - Highest daily census: 37 in September, 2012



Average Daily Census for NAS babies					
	1 st Quarter (JAN-MAR) 2 nd Quarter (APR-				
2011	8	13			
2012	29	24			
2013	28	26			

Typical course of treatment

- 70 % of NAS babies
 - Wean in 20 days
 - No adjunctive meds
 - LOS 24 days

- 30 % of NAS babies
 - Wean in 60 days
 - Require adjunctive meds
 - Phenobarbital (27%)
 - Phenobarbital +Clonidine (7%)
 - LOS 68 days
 - (longest LOS = 155 days)



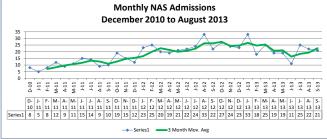
NAS Project Summary Report 10/9/2013

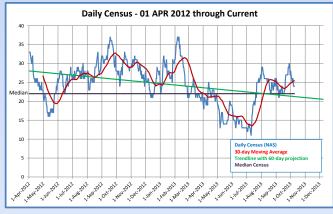
Project Statistics						
Proje	Project start date: 22 NOV 2010; 1052 days; (35 months)					
Projected annual admissions: 257 (based on CY 2013 admissions to date: 198)						
Admissions Discharges NAS diagnosis at D/C ≥ 35 weeks < 35 weeks						
Overall	631	606		593	38	
2010	11	11		10	1	
2011	139	139		122	17	
2012	283	283		268	15	
2013	198	173	172 (99.4%)	193	5	
LOS Statistics						

Average LOS pre-7 NOV 2011:	40	Average LOS post-/ NOV 2011:	33	
Number of Pat	ients	Average LOS		
ϵ	606	35 days (7-155 days)		
552 (91.1	L%)	30 days; (7-60 days)		
429 (70.8	3%)	25 days; (7-40 days)		
313 (51.7	7%)	21 days: (7-30 days)		

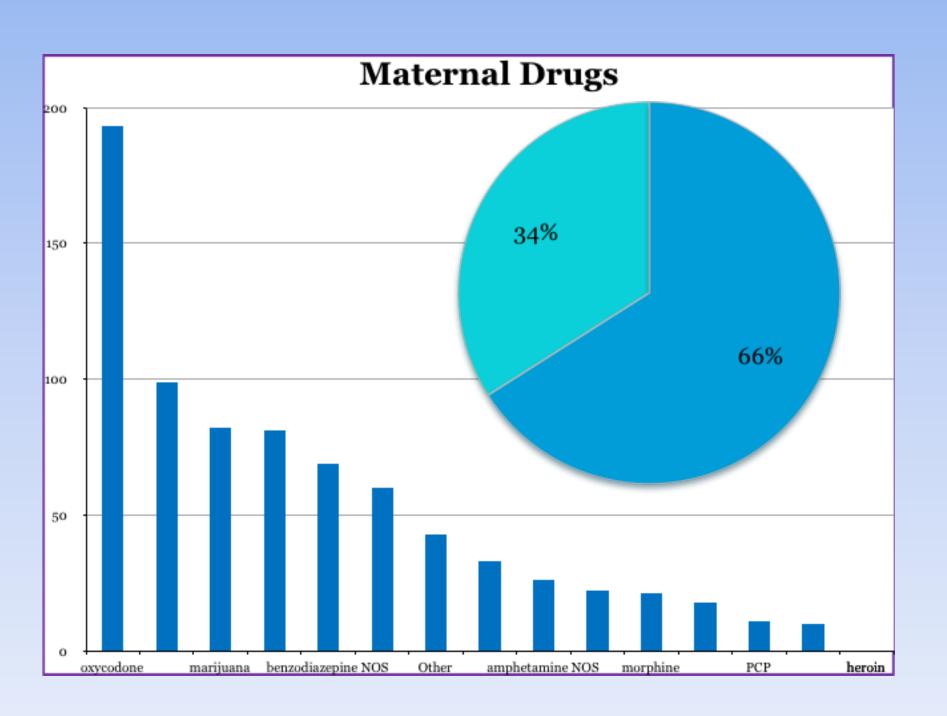
		100 100 1	100 40 1		
		LOS ≤ 40 days	LOS > 40 days	(00.00()	
	Number	429 patients, (70.8%)	177 patients,	(29.2%)	
Inpatient days after		4 days	9 days		
Inpatient days after morphine v		9 days	15 days		
W	eaning Stati	stics (Morphine)			
		Overall	≥ 35 wk	< 35 wk	
Num	nber Weaned:	607	567	38	
Α	verage wean:	27 days	27	22	
Average wean post NIC	U-III opening:	26 days			
Inpatient days post-w	ean (average)	7	7	11	
Overall Longest wean: 155 days Shortest wean: 7 days.					
Pharmacotherapy					
Most common initial dose: 40 mcg, Highest Initial Dose: 500 mcg, Highest overall dose: 540 mcg					
No	Adjunct Rx:	417	(66.1%)		
Ph	enobarbital:	170	(26.9%)		
Phenobarb	+ Clonidine:	42	(6.7%)		
	Clonidine:	2	(0.3%)		
	Nystatin:	127	(20.1%)		
	Referra	al Source			
FS Regional: 364	(58%)	ITU	MCK: 2 (0%)	
Oak Ridge Methodist: 69	(11%)	Tak	oma: 2 (0%)	
Morristown Hamblen: 65	(10%)	Cocke Co	unty: 2 (0%)	
Leconte: 41	(6%)	ETC	HED: 2 (0%)	
Cumberland Med Center: 33	(5%)	Atl	nens: 2 (0%)	
Lakeway Medical Center: 17	(3%)	0	ther: 5 (1%)	
FS ParkWest: 17	(3%)	Includes: Jefferson Me	morial, Roane	Medical	
Jellico: 6	(1%)	Center, St. Marys-Mer			
Sweetwater: 4	(1%)	Home		."	

Census	Monthly Ad	missions	
Current Census:	25	Jul-2012	24
Last 7 days percent NAS in NICU:	50%	Aug-2012	33
Overall NAS Ratio:	46%	Sep-2012	22
Highest Census:	37	Oct-2012	27
Average Overall Census:	21	Nov-2012	24
6 month-Average Census (JAN-JUN) 2013:	22	Dec-2012	23
Quarterly Average Census		Jan-2013	33
4th quarter (OCT-DEC) 2011:	18	Feb-2013	18
1st quarter (JAN-MAR) 2012:	29	Mar-2013	25
2nd quarter (APR-JUN) 2012:	24	Apr-2013	19
3rd quarter (JUL-SEP) 2012:	29	May-2013	19
4th quarter (OCT-DEC) 2012:	28	Jun-2013	11
1st quarter (JAN-MAR) 2013:	27	Jul-2013	25
2nd quarter (APR-JUN) 2013:	22	Aug-2013	22
3rd quarter (JUL-SEP) 2013:	23	Sep-2013	21

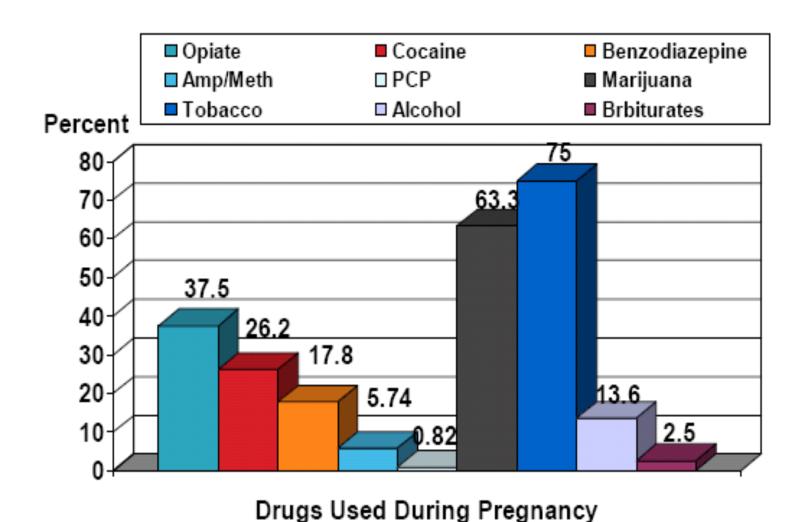




East Tennessee Children's Hospital Confidential



Prevalence of Substance Use Among Drug Using Pregnant Women (%)

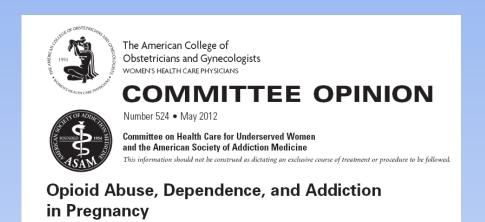


Why do expectant mothers use drugs?

- Prior injury / chronic pain
- Medical need for pain management
 - Appropriately managed
 - Inappropriately managed
- In a substance abuse treatment program (MAT)
- Confusion between symptoms of withdrawal and early pregnancy.
- Family/social environment

Why do MDs continue to prescribe?

- ACOG Guidelines and SAMSHA Guildelines recommend to continue MRT (methadone or buprenorphine)
- · "Lesser of two evils"
 - Risky drug-seeking behaviors
 - Goals of quelling cravings
 - Prevent mini-withdrawals
 - Ceiling effect of being in treatment
 - Methadone, suboxone, subutex
 - Reveal danger of I.V. suboxone



- "Standard of care for pregnant women with opioid dependence: referral for opioid-assisted therapy
- Abrupt d/c of opioids can result in preterm labor, fetal distress, or fetal demise
- During intrapartum/postpartum period, special considerations are needed...ensure appropriate pain management, prevent postpartum relapse, prevent risk of overdose, ensure adequate contraception.

Intrauterine Drug Exposure

The presence or absence of NAS

does not indicate the severity of intrauterine drug exposure or abuse.



The Newborn with Intrauterine Drug Exposue

- Low birth weight
- Small Head Circumference
- Abnormal EEG pattern / Seizures
- Signs of physical dependency withdrawal
 - Signs of effects may last for months
 - Hypertonic
 - Tremors
 - Periods of irritability

Opiod Intra-Uterine Drug Exposure

OPIATES or OPIOIDS

Morphine

Heroin

Codeine

Semi-synthetic and synthetic opioids

Oxycodone
Hydrocodone
Methadone
Buprenorphine
Tramadol

Drug source may be legal or illegal (diverted) Used as directed, misused, or abused...

The baby doesn't know the difference

They will affect brain
development
Effects dependent on stage of
gestation of the fetus had drug exposure

Fetal Brain Development

Majority of development occurs in first 12 weeks

2wks: Brain is first organ to develop

4wks: cerebral hemispheres appear

5-6wks Cranial nerves identifiable

6-7wks Brain wave activity begins

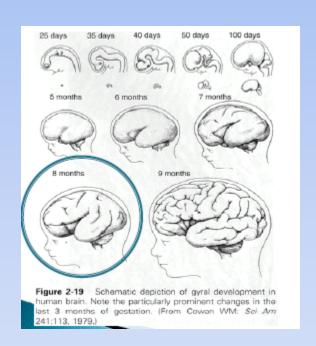
7-8wks Brain represents 43% of embryo

8-9wk Begin to experience light sense of touch

13wks Most of body has sensation to touch

19wks Daily cycles of biological rhythms

26-38wks Brain increases in weight by 400-500%



Prenatal Exposure & Brain Development

- Behavior Teratology Framework: Agents that are relatively harmless to the mother could still have a harmful effect or consequences to the fetus
 - Based on <u>2 principles</u> (Vorhees CV in Hutchins DE, Editor. Prenatal abuse of licit and illicit drugs NYAS 1989, p31-41.)
 - Vulnerability of the CNS to injury extends beyond fetal, neonatal, and infancy stage
 - Most frequent manifestations of CNS injury: not grossly malformed brain but in functional abnormalities that may not be detected at birth, but later in childhood, adolescence, or adulthood.
- Related to Barker hypothesis: Any perturbation during fetal development may have enduring effects on later behavior.

Brain Development

Neuroimaging showed physiological brain changes in drug-exposed infants vs. non-exposed infants

Temporal/frontal lobe changes

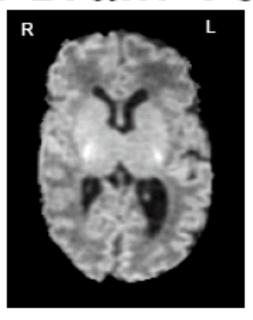
Permanent, can not be "fixed"

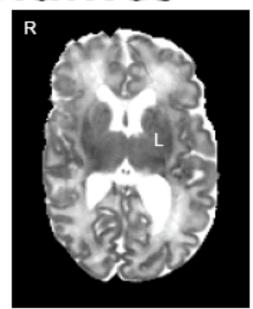
Nurturing and environment can mitigate damages

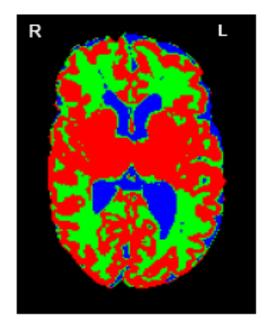


MRI: Brain Volumes

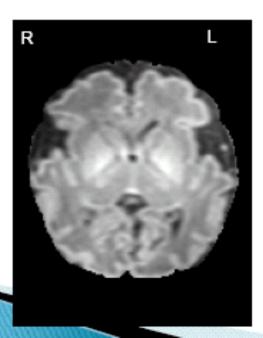
Term No opiate exposure

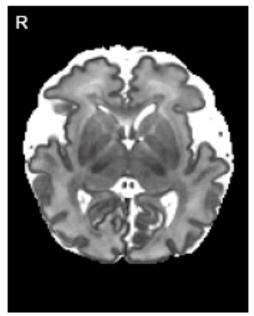


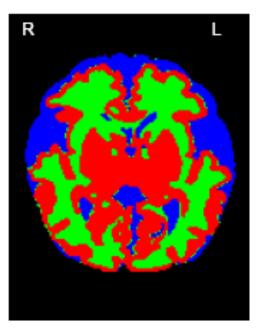




Term Lortab use during pregnancy







LONG-TERM EFFECTS

- BRAIN DEVELOPMENT
- SIDS
- SLEEP
- NUERODEVELOPMENTAL DELAYS
- BEHAVIOR REGULATION
- SENSORY PROCESSING
- COGNITIVE/LEARNING DELAYS
- PSYCHOSOCIAL IMPLICATIONS

Intra-Uterine Exposure to Other Drugs

Marijuana

Decreased problem-solving skills

Decreased attention

Impulsivity

Decreased memory, memory processing, even at 18 Y

Methamphetamines

Memory

Impulse control

Decreased goal setting

Decreased flexibility

Increase in ADHD

"The focus has turned to the long-term developmental outcome of children with prenatal drug exposure, especially as they reach adolescence."

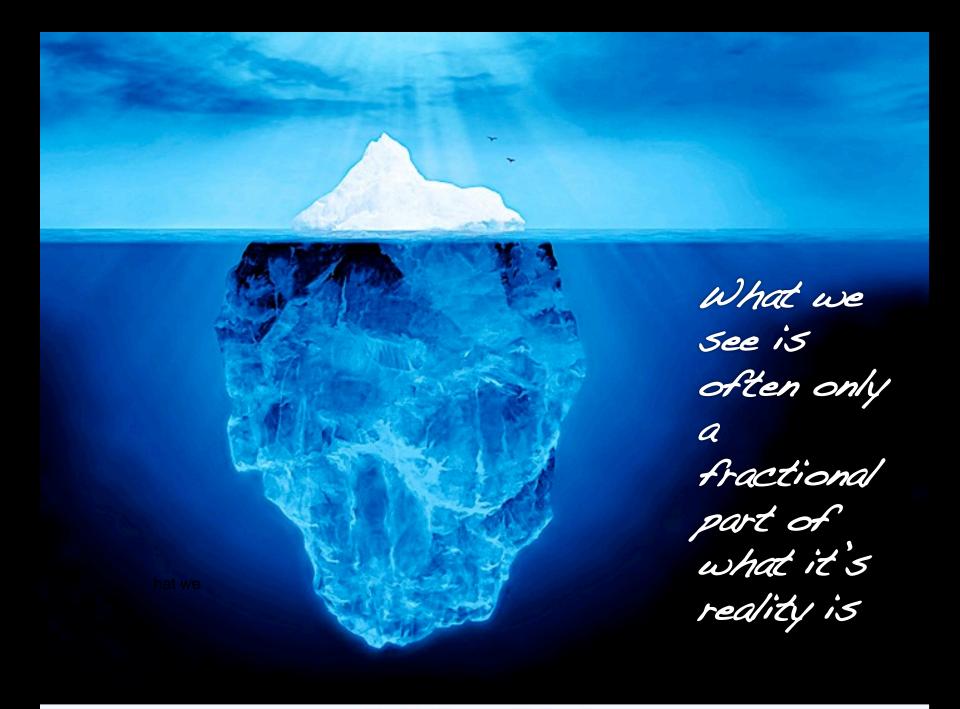
-Henrietta Bada, MD, MPH

The Hidden Epidemic:
Living with Neonatal Abstinence Syndrome (NAS)
and What the Future Holds
September 13, 2013

Substance Use Disorders

"Addiction is a developmental disorder of adolescence"

Dr. Nora Volkow, Director, National Institute on Drug Abuse



Public Health Issues

- NICU beds taken by infants whose only need is withdrawal treatment
- Behavioral issues in childhood
 - Schools teacher retraining
- Potential long-term public health issue
 - Generational addiction problems
 - 2nd and 3rd generational behaviors sustained
 - Genetic predisposition?
 - Does intrauterine exposure activate gene in utero?
 - Does NAS treatment complicate addictive tendencies?

TIPQC Tennessee Initiative for Perinatal Quality Care

State wide recognition of NAS as a growing problem Spring 2011

Elected as statewide quality improvement initiative

Toolkit Development:

Menu of Potentially Better Practices for the care of the NAS infant RedCap Data collection Grant for participation

The Levels of Prevention

	PRIMARY Prevention	SECONDARY Prevention	TERTIARY Prevention
Definition	An intervention implemented before there is evidence of a disease or injury	An intervention implemented after a disease has begun, but before it is symptomatic.	An intervention implemented after a disease or injury is established
Intent	Reduce or eliminate causative risk factors (risk reduction)	Early identification (through screening) and treatment	Prevent sequelae (stop bad things from getting worse)
NAS Example	Prevent addiction from occurring Prevent pregnancy	Screen pregnant women for substance use during prenatal visits and refer for treatment	Treat addicted women Treat babies with NAS

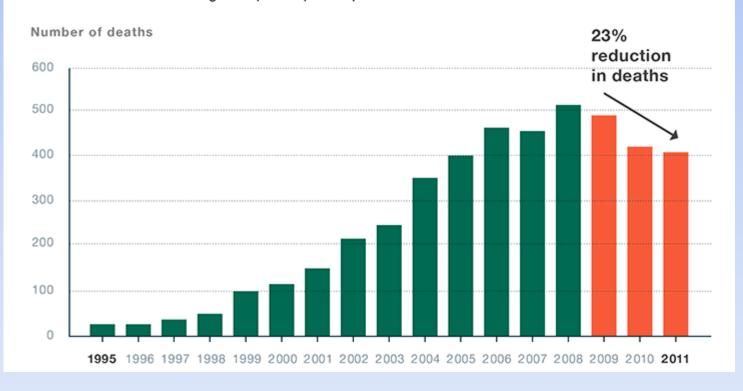
2. Support safe prescribing.

Doctors and other prescribers need clear guidelines to determine the appropriate amount of painkillers needed.



Washington: responsible prescribing

In 2007, the state of Washington issued voluntary prescribing guidelines. Passed into law in 2010, the guidelines reversed a decade-long trend of increasing fatal prescription opioid overdoses.



National Safety Council. Prescription Nation Addressing America's Prescription Drug Epidemic http://www.nsc.org/safety_home/PrescriptionDrugOverdoses/Documents/Prescription%20Nation%20Report.pdf. Accessed Oct. 15, 2013 .

DOH NAS Efforts in TN

- Spring 2012
 - "Prescription Safety Act" required prescribers to register with Controlled Substances Monitoring Database (CSMD)
 - Growing awareness of increasing NAS incidence among neonatal providers
 - Initial discussions between public health (TN Department of Health) and Medicaid (TennCare)



NAS Subcabinet Working Group

- Convened in late Spring 2012
- Committed to meeting every 3-4 weeks
- Cabinet-level representation from Departments:
 - Public Health (TDH)
 - Children's Services (DCS)
 - Human Services (DHS)
 - Mental Health and Substance Abuse Services (DMHSAS)
 - Medicaid (TennCare)
 - Children's Cabinet



NAS Subcabinet Working Group

- Working principles:
 - Multi-pronged approach
 - Best strategy is primary prevention but clearly must address secondary and tertiary prevention
 - Each department progresses independently, keep group informed of efforts
 - Supportive rather than punitive approach



Opiod Prescribing Guidelines Task Force

- Pain and addiction treatment specialists
- Primary care physicians
- Pharmacists
- Perinatal Specialists
- Midwifery
- Neonatology
- Legal
- State medicaid
- Charged by commissioner to "Be bold" in approach
- Implementation Goal: Jan 1st, 2014

NAS Research Steering Committee

- Board identified Spring 2013
- Monthly conference calls
- Invitations sent to experts from across the state for September 25th 2013
- Goal: Identify 3-5 potentially answerable research questions surrounding NAS
- Identify groups to begin to look at developing research framework for each question

•

NAS—Primary Prevention

- Prevent addiction from occurring
 - Letter to FDA encouraging black box warning
 - Provider education
 - Letter to providers to increase awareness
 - Possibly add to "responsible prescribing" CME
 - TennCare limitations on opioid availability
 - Requirement for counseling as part of prior authorization
 - Limitations on available quantity



Request for Black Box Warning



STATE OF TENNESSEE

DEPARTMENT OF HEALTH

JOHN J. DREYZEHNER, MD, MPH COMMISSIONER

BILL HASLAM GOVERNOR

November 1, 2012

Margaret Hamburg, M.D. Commissioner U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Commissioner Hamburg:

We write out of grave concern for the health, developmental and life course consequences for babies whose antenatal environment includes substantial opioid analgesic exposure. We believe that a "black box warning" for these medications would help assure that women of childbearing age and their health care providers are aware of the serious risks associated with narcotic use during pregnancy. Possible content for the warning may be as follows:

WARNING: USE OF NARCOTIC ANALGESICS IN WOMEN OF CHILD BEARING AGE MAY CAUSE NEONATAL ABSTINENCE SYNDROME

This message would also promote a critical dialog between the patient and provider regarding considerations in planning for pregnancy or prevention of unintended pregnancy for women who are benefiting therapeutically from these powerful medications or who may be at risk for abusing them. This





U.S. Food and Drug Administration

Protecting and Promoting Your Health



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Drugs

Medical Devices

Radiation-Emitting Products

Vaccines, Blood & Biologics

Animal & Veterinary

Cosmetics

Tobacco Products

News & Events

Home News & Events Newsroom Press Announcements





FDA NEWS RELEASE

For Immediate Release: Sept. 10, 2013

Media Inquiries: Morgan Liscinsky, 301-796-0397, morgan.liscinsky@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

En Español

FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics New boxed warning to include neonatal opioid withdrawal syndrome

The U.S. Food and Drug Administration today announced class-wide safety labeling changes and new postmarket study requirements for all extended-release and longacting (ER/LA) opioid analgesics intended to treat pain.

"The FDA is invoking its authority to require safety labeling changes and postmarket studies to combat the crisis of misuse, abuse, addiction, overdose, and death from these potent drugs that have harmed too many patients and devastated too many families and communities," said FDA Commissioner Margaret A. Hamburg, M.D. "Today's action demonstrates the FDA's resolve to reduce the serious risks of long-acting and extended release opioids while still seeking to preserve appropriate access for those patients who rely on these medications to manage their pain."

The FDA is also requiring a new boxed warning on ER/LA opioid analgesics to caution that chronic maternal use of these products during pregnancy can result in neonatal opioid withdrawal syndrome (NOWS), which may be life-threatening and require management according to protocols developed by neonatology experts. NOWS can occur in a newborn exposed to opioid drugs while in the mother's womb. Symptoms may include poor feeding, rapid breathing, trembling, and excessive or high-pitched crying.

The updated indication further clarifies that, because of the risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death, these drugs should be reserved for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain; ER/LA opioid analgesics are not indicated for as-needed pain relief.

"The FDA's primary tool for informing prescribers about the approved uses of medications is the product labeling," said Douglas Throckmorton, M.D., deputy director for regulatory programs in the FDA's Center for Drug Evaluation and Research. "These labeling changes describe more clearly the risks and safety concerns associated with ER/LA opioids and will encourage better, more appropriate, prescribing, monitoring and patient counseling practices involving these drugs."

Recognizing that more information is needed to assess the serious risks associated with long-term use of ER/LA opioids, the FDA is requiring the drug companies that make these products to conduct further studies and clinical trials. The goals of these postmarket requirements are to further assess the known serious risks of misuse,

TennCare Prior Authorization Form

		TEN following info		***All F	A forms	may	be fo		Lo by acce	ng essing	Ac http	tinç os://tr	ization Forr g Narcotics m.providerportal.s rocess can be d	sxc.c				
Member Information																		
		Last Name											First Name					
		ID Number											Date of Bir	th	-		-	
		Prescribe	r Inf	orma	ation													
For female patients between the ages of 18 & 45, please complete questions 10 -12																		
10. The use of opioid analgesics during pregnancy has been associated with neonatal abstinence syndrome Has this patient been																		
counseled regarding the risks of becoming pregnant while receiving this medication, including the risk of neonatal abstinence																		
syndrome?	Yes	□No																
11. Is this patient currently utilizing a form of contraception?																		
12. Has access to contraceptive services been offered o this patient? Yes No																		

NAS—Primary Prevention

Prevent pregnancy from occurring

- Provider education
 - Counseling by providers at initial prescription
 - Promotion of contraceptives, particularly longacting reversible contraceptives (LARCs)
- Work with non-traditional partners to promote counseling re: addition during pregnancy and contraceptives
 - A&D
 - Pain clinics
 - Drug courts



NAS—Secondary Prevention

- Identify pregnant women who may be opioid addicted
 - Identify reproductive-aged women via CSMD whose fill patterns suggest risk of dependence
 - Referral to TennCare managed care organization case management programs
 - Screen women for drug use
 - Consent of patient
 - Supportive rather than punitive approach



NAS—Tertiary Prevention

- Minimize complications for women who are addicted (and their neonates)
 - Can addicted pregnant women be weaned?
 - What are best strategies for treating NAS infants?



- Previous estimates of NAS incidence came from:
 - Hospital discharge data (all payers but ~18 month lag)
 - Medicaid claims data (only ~9 month lag but only includes Medicaid)
- Need more real-time estimation of incidence in order to drive policy and program efforts



- Health Commissioner has authority to add diseases to Reportable Disease list
 - Reportable disease—Any disease which is communicable, contagious, subject to isolation or quarantine, or epidemic...
 - Event—An occurrence of public health significance and required by the Commissioner to be reported in the List.
- Add NAS to state's Reportable Disease list
 - Effective January 1, 2013



- Identified stakeholders:
 - Birthing hospitals
 - Hospital associations
 - Providers and professional groups
 - Obstetricians, neonatologists/pediatricians
 - Department of Children's Services (DCS)
 - State Public Health Epidemiologists
 - Addressed Concerns



- Approach to Stakeholder Concerns:
 - Transparency, transparency, transparency
 - Listen and incorporate feedback into design of reporting tool
 - Joint messaging with DCS re: intent and interagency data sharing
 - Engage end-users in piloting system (test cases with subsequent revisions)



- Reporting hospitals/providers submit electronic report (SurveyMonkey)
- Reporting Elements
 - Case Information
 - Diagnostic Information
 - Source of Maternal Exposure



Drug Dependent Newborns (Neonatal Abstinence Syndrome)

Surveillance Summary For the Week of October 6-October 12, 2013

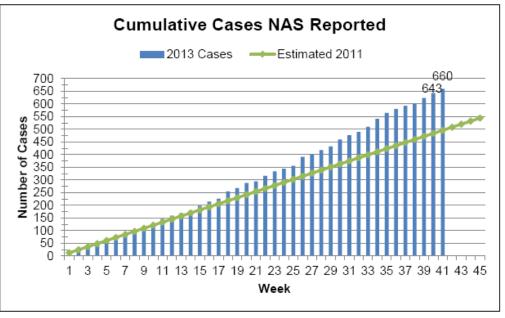
(Week 41)1

Reporting Summary (Year-to-date)

Cases Reported: 660 Male: 383 Female: 277

Unique Hospitals Reporting: 49

Maternal County of Residence (By Health Department Region)	# Cases	% Cases
Davidson	33	5.0%
East	181	27.4%
Hamilton	11	1.7%
Jackson/Madison	1	0.2%
Knox	71	10.8%
Mid-Cumberland	46	7.0%
North East	100	15.2%
Shelby	14	2.1%
South Central	22	3.3%
South East	10	1.5%
Sullivan	67	10.2%
Upper Cumberland	85	12.9%
West	19	2.9%
Total	660	100%



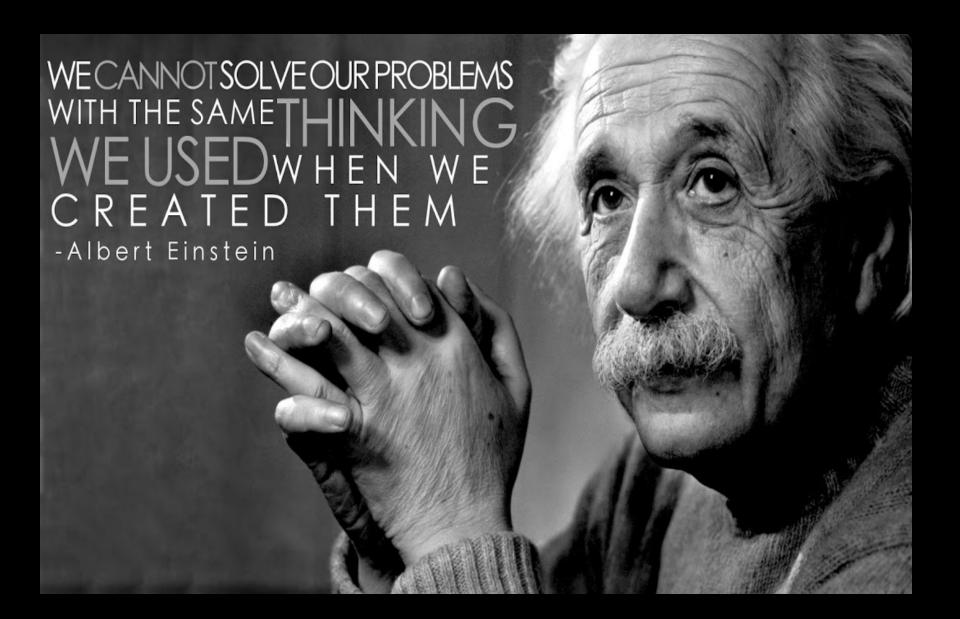
Source of Maternal Substance (if known) ²	# Cases²	% Cases
Supervised replacement therapy	292	44.2%
Supervised pain therapy	134	20.3%
Therapy for psychiatric or neurological condition	51	7.7%
Prescription substance obtained WITHOUT a prescription	262	39.7%
Non-prescription substance	185	28.0%
No known exposure but clinical signs consistent with NAS	11	1.7%
No response	15	2.3%

- 1. Summary reports are archived weekly at: http://health.tn.gov/MCH/NAS/NAS Summary Archive.shtml
- 2. Multiple maternal substances may be reported; therefore the total number of cases in this table may not match the total number of cases reported.

Key Points

- The impact of NAS does not end in the NICU.
- Long-term impact to both the healthcare system and society is significant.
- Prevention of unintended pregnancy is crucial.
- · Prenatal care with supervised replacement therapy is critical.
- We must do all we can to promote prenatal care and substance abuse treatment/counseling in this high-risk population.
- Incentives to seek help may allow more opportunities for the woman to receive successful treatment with lifelong benefits.
- RX Substance abuse prevention and complete rehabilitation

Preventable





Innovation— any new idea—by definition will not be accepted at first. It takes repeated attempts, endless demonstrations, monotonous rehearsals before innovation can be accepted and internalized by an organization. This requires courageous patience." - Warren **Bennis**

